

Patient Information Sheet

Escitalopram oxalate (marketed as Lexapro)

This is a summary of the most important information about Lexapro. For details, talk to your healthcare professional.

FDA ALERT [05/2005]—Suicidal Thoughts or Actions in Children

Patients with depression or other mental illnesses often think about or attempt suicide. Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior should be evaluated by their healthcare professional right away.

Although Lexapro is prescribed for children, it has not been approved by FDA for use in children.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Lexapro?

Lexapro is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs).

Lexapro tablets and oral solution are used to treat:

- Depression
- Generalized Anxiety Disorder (GAD)

Who Should Not Take Lexapro?

Never take Lexapro if you are taking another drug used to treat depression called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Lexapro close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate). Marplan (isocarboxazid), and other brands.

What Are The Risks?

- Suicidal thoughts or actions: See FDA Alert.
- **Stopping Lexapro:** Do not stop taking Lexapro suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.

- **Bleeding problems:** Lexapro may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen and naproxen), or other drugs that affect bleeding.
- Mania: You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion) even if you are not taking Lexapro close in time with a MAOI.
- Pregnancy: Tell your healthcare professional if you are
 or may be pregnant because babies delivered to mothers
 taking Lexapro late in pregnancy have developed
 problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- Other side effects include difficulty sleeping, nausea, increased sweating, fatigue, and sleepiness.
- Tell your healthcare professional about all your medical conditions, especially if you have liver or kidney disease. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Do not take Lexapro with Celexa (citalopram), another drug used to treat depression, because they are very similar and you could get an overdose.
- Lexapro may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take.
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Lexapro?

Lexapro is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.

Is There Anything Else I Need to Know?

You can get more information about antidepressants at: http://www.fda.gov/cder/drug/antidepressants/default.htm

Lexapro FDA Approved 2002 Patient Information Sheet Revised 05/2005

